

Message Text

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PAGE 01 STATE 064716
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-09 ISO-00 OES-06 /034 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH:BHOLLAND
EA/J:DFSMITH(INFO)
EUR/NE:REWOODS(INFO)
EUR/CE:SKLINGAMAN(INFO)
EA/ANP:HTNELSON(INFO)

-----240209Z 066914 /70

P 232224Z MAR 77
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY
AMEMBASSY CANBERRA
AMEMBASSY WELLINGTON
AMEMBASSY STOCKHOLM
AMEMBASSY BERN

UNCLAS STATE 064716

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, JA, NZ, SW, SZ

SUBJECT: DEFECTIVE MEDICAL DEVICE (RECALL T-032/U33-7)

FDA ADVISES OF THE FOLLOWING DEVICE RECALLS:

- T-U32-7, MONAGHAN "MODEL 3UU" ANESTHESIA VENTILATOR
- WITH GAS SCAVENGER SYSTEM, KIT PART NUMBER 16290,
- DISTRIBUTED SINCE 9/1/76, SERIAL NUMBERS 08760126/36,
08760146/54,08761590/94,08761596/604

- T-033-7, MONAGHAN VENTILATOR SCAVENGER SYSTEM,
- KIT PART NUMBER 16290, FOR SCAVENGING OF WASTE

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- ANESTHETIC AGENTS FROM MONAGHAN OR OHIO
- MODEL 300 ANESTHESIA VENTILATORS DISTRIBUTED
- SINCE 9/1/76. THE KIT IS ALSO KNOWN AS A
- DUMP VALVE KIT.

KITS DISTRIBUTED PRIOR TO 9/1/76 HAD A DIFFERENT
PART NUMBER, AND KITS WHICH MAY BE DISTRIBUTED AFTER

THE RECALL IS COMPLETED WILL ALSO HAVE A DIFFERENT
PART NUMBER.

MANUFACTURER/RECALLING FIRM:

MONAGHAN, A

- DIVISION OF SANDOZ, INC.
- 4100 EAST DRY CREEK ROAD
- LITTLETON, COLORADO 80122

REASON FOR RECALL RECOMMENDATION:

THE ANESTHETIC GAS SCAVENGER SYSTEM IN A MONAGHAN MODEL
300 ANESTHESIA VENTILATOR MALFUNCTIONED ON TWO DIFFERENT
OCCASIONS DURING SURGERY. THE MANUFACTURER DETERMINED
THAT THE PLASTIC RETAINER WITHIN THE ASSEMBLY OF THE
SCAVENGER SYSTEM KIT WAS DEFECTIVE CAUSING THE SILICONE
EXHALATION VALVE TO STICK TO THE RETAINER. THIS RESULTS
IN THE VENTING OF ALL ANESTHESIA GASES FROM THE VENTILATOR
CIRCUIT. WHEN THIS CONDITION OCCURS THE PATIENT WILL
NOT BE VENTILATED.

POSTS ARE REQUESTED TO DETERMINE IF CONSIGNEES HAVE
RECEIVED PRODUCT OR ALERT LETTER DATED NOVEMBER 18, 1976
FIRMS RECALL LETTER ENCLOSES A SKETCH AND INSTRUCTIONS
WITH REPLACEABLE PART INDICATING THAT NEW PART SHOULD
BE INSTALLED AS INDICATED IN DIAGRAM AND PART REPLACED
SHOULD BE RETURNED TO MONAGHAN.

FOREIGN CONSIGNEES AS FOLLOWS:

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CROWE CO LTD
ZOLLFREILGER AIRPORT
BASEL, MULHAUSEN
CH 4030
BASEL SWITZERLAND

MEDICAL TELETRONICS LTD.
2 SIRUS ROAD
AIR NEW ZEALAND CARGO BLD
AUCKLAND ARPT
NEW ZEALAND

TELETRONICS PTY LTD
2 SIRUS RD.
LANE COVE NSW 2066
AUSTRALIA

SCANDIA METRIC

ATTN: MR. GUNNELO, ESQ.
P. O. BOX 17118
SOLONA 1, SWEDEN

SANDOZ YAKUHHN KK
5 CHROME MINATO KU
12-4 MINAMI AOYAMA
TOKYO JAPAN
VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 23-Mar-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE064716
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770100-0574
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770329/aaaaazfv.tel
Line Count: 125
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: b95a20b3-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 28-Sep-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3016893
Secure: OPEN
Status: NATIVE
Subject: DEFECTIVE MEDICAL DEVICE (RECALL T-032/U33-7) FDA ADVISES OF THE FOLLOWING DEVICE RECALLS: - T-U32-7, MONAGHAN
"MODEL 3UUV" ANESTHESIA VENT
TAGS: OGEN, ETRD, EIND, TBIO, AS, JA, NZ, SW, SZ
To: TOKYO CANBERRA MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/b95a20b3-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009